IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Solomon S. Steiner and Bryan R. Wilson

Serial No.: 09/766,362 Art Unit: 1615

Filed: January 19, 2001 Examiner: Humera Sheikh

For: *DRY POWDER FORMULATIONS OF ANTIHISTAMINE FOR NASAL ADMINISTRATION*

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Commissioner for Patents
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REPLY BRIEF TO EXAMINER'S ANSWER

Sir:

This is a reply brief to the Examiner's Answer mailed May 20, 2005, in the above-referenced application. Submitted with this Reply Brief is a Request for Oral Hearing. The Commissioner is hereby authorized to charge $500, the fee for a Request for Oral Hearing for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

(8) ARGUMENTS

Appellants affirm all of the arguments made in the Appeal Brief.

Contrary to the Examiner's assertion on page 8 of the Examiner's Answer, the limitation in claim 1, "in a form suitable for nasal administration" is a functional limitation, not an

"intended use". M.P.E.P. § 2173.05 (g) defines functional limitations and explains that they "must be evaluated and considered, just like any other limitation of the claim". *Id.* Therefore, the Examiner should have considered this limitation in his analysis of the patentability of the claims.

Steiner notes that drugs may be administered topically in the form of an ointment or cream (see col. 13, lines 1-2), a solution or suspension for parenteral, intradermal or subcutaneous administration (see col. 11, lines 50-51), or may be in an oral dosage form, such as in the form of a tablet, pill, capsule or troche (see col. 11, lines 66 until col. 12, line 1). None of the forms are suitable for nasal administration. As noted in the Appeal Brief, the only reference to the nasal tract occurs when Steiner mentions that microparticles can include a diagnostic imaging agent useful for imaging the nasal tract (col. 13, lines 17-21). However, Steiner does not disclose the form in which the microparticles are administered to image the nasal tract. In contrast, Steiner lists a number of different dosage forms which are not suitable for nasal administration. For example, formulations that are suitable for injection are administered in solution, in a volume that suspends the particles so that they are readily distributed at the site of administration. In contrast, a formulation suitable for nasal administration cannot be suspended in a quantity of liquid since this would wash away the particles from the site of deposition. Additionally, formulations for oral administration are in the form of a tablet or capsule, which is not a form suitable for nasal administration. Further, Steiner does not suggest modifying the

formulations to make them suitable for nasal administration. Therefore claim 1 and its dependent claims, claims 2, 4, and 5, are non-obvious in view of Steiner.

Independent claims 7 and 14 each contain a limitation that is similar to the limitation in claim 1 discussed above. Claim 7 specifies that the dry powder is "in a dosage formulation for administration to the nasal region". Claim 14 specifies that the dry powder is "suitable for nasal administration". These are also functional limitations. As noted above with respect to claim 1 and its dependent claims, Steiner does not disclose or suggest "microparticles in a dosage formulation suitable for administration to the nasal region" or a "dry powder suitable for nasal administration". Therefore claim 7 and its dependent claims, claims 9 and 12, and claim 14 and its dependent claims, claims 15, 17 and 18, are non-obvious over Steiner.

Claims 7, 9 and 12 are non-obvious over Steiner

Independent claim 7 and its dependent claims define a drug delivery device for nasal administration. Claim 7 specifies that the device contains a device for delivering a measured dose of the drug to the nasal mucosa. Steiner does not disclose or suggest a device for delivering a measured dose of a drug to the nasal mucosa. The only drug delivery devices disclosed by Steiner are ampoules, disposable syringes, and multiple dose vials made of glass or plastic, which are suitable for delivering a drug parenterally (see col. 11, lines 60-63). Steiner notes that drugs may be administered topically in the form of an ointment or cream (see col. 13, lines 1-2) or may be injected subcutaneously, intramuscularly or into the peritoneum using a standard gauge needle (see col. 12, lines 43-52). None of the devices or methods of administration are

suitable for delivering a measured dose of the drug to the nasal mucosa, as required by claim 7 and its dependent claims. Further Steiner does not suggest using a device suitable for administering a drug to the nasal mucosa. Therefore, claims 7, 9, and 12 are non-obvious over Steiner.

Claims 14, 15, 17, and 18, are non-obvious over Steiner

Independent claim 14 and its dependent claims define a method for administering a drug to the nasal region of a patient. Claim 14 specifies that the method requires nasally administering a dry powder suitable for nasal administration. Steiner does not disclose or suggest nasally administering a dry powder. Steiner discloses a variety of other methods of administration, such as oral administration (see col. 11, line 66 until col. 12, line 4), topical administration of an ointment of cream (see col. 12, line 60 until col. 13, line 2), and parenteral administration (see col. 11, lines 61-63). As noted in the Appeal Brief, the only reference to the nasal tract occurs when Steiner mentions that microparticles can include a diagnostic imaging agent useful for imaging the nasal tract. However, Steiner does not disclose the form in which the microparticles are administered to image the nasal tract. Further, Steiner does not suggest nasal administration of a dry powder. Therefore, claims 14, 15, 17, and 18 are non-obvious over Steiner.

Claims 3, 8, 10, 16, 20, and 21 are non-obvious

There is no teaching to combine Steiner and Illum

Illum describes bioadhesive microspheres that form a gel upon contact with nasal mucosa (col. 3, lines 2-9 and col. 6, lines 13-15). Illum lists a number of suitable materials for forming the microspheres. All of the listed materials are polymers, such as starch, gelatin, casein, dextrans, alginate, agarose, albumin, collagen, chitosan, polyvinylacetate, and hyaluronic acid esters (col. 6, lines 15-19). Illum does not disclose a non-polymeric material that does not form a gel when placed on mucosal surfaces, such as a diketopiperazine.

Illum emphasizes the importance of bioadhesive systems. These microparticles allow for an increased period of contact with the mucosal surface in the nasal cavity (see col. 5, lines 19-23 and col. 8, lines 49-51). Thus, Illum teaches away from using microparticles that do not form gels.

In contrast, Steiner discloses microparticles formed of diketopiperazines and an encapsulated drug. Steiner does not disclose or suggest using gel-forming polymers in its drug delivery system. Therefore there is no suggestion in Steiner or Illum to combine these references; and claims 3, 8, 10, 16, 20, and 21 are non-obvious.

(9) SUMMARY AND CONCLUSION

For the foregoing reasons and those in the Appeal Brief, Appellants submit that claims 1-5, 7-12, and 14-21 are non-obvious.

Respectfully submitted,

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